

Update on the NCI Cancer Centers Program

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Outline

- Cancer Center Program Funding
- History of the CCSG
- Funding Opportunity Announcement
 - What hasn't changed
 - What has changed
 - New components
- Research Programs, Shared Resources, Cancer Research Career Enhancement and Related Activities, and Community Outreach and Engagement, Consortium status

CCSG funding

<u>Fiscal Year</u>	<u>CCSG Total Costs (millions)</u>	<u>Number of Centers</u>
2010	271.5	66
2011	256.7	66
2012	258.1	67
2013	244.8	68
2014	258.2	68
2015	261.5	69
2016	275.6	69
2022	303.4 (?)	69+

History of the Cancer Center Support Grant as a Mechanism

- 1973-2011: Guidelines issued by NCI Cancer Centers Branch/Office of Cancer Centers
- 2012: CCSG issued for the first time as a Funding Opportunity Announcement per NIH rule – contents ultimately controlled by NIH Office of Extramural Research; separate Comprehensiveness review terminated
- 2013: CCSG FOA reissued to mandate electronic submission (ASSIST) per NIH rule; no changes to content
- 2017: CCSG revision published Dec 22, 2016
- Next revision – 2020 or 2018 (!)

2017 CCSG – What hasn't changed

- Director's Overview and 6 Essential Characteristics
- Clinical Protocol and Data Management
- Protocol Review and Monitoring System
- Data Safety Monitoring Plan
- Catchment Area

“The **catchment area** must be defined and justified by the center, based on the geographic area it serves. It must be population based, e.g. using census tracts, zip codes, county or state lines, or other geographically defined boundaries. It must include the local area surrounding the cancer center.”

- Inclusions
- Comprehensiveness

Research Programs

- New minimum
- Review criteria reworded

2013 – What is the overall scientific quality of the Program?

2017 - What is the impact of the research of the program, as demonstrated by:

- Publications in top-tier journals for that field
- Widely-cited publications
- Generation of paradigm-changing hypotheses or scientific methods that move the field forward
- Movement of scientific findings through the translational pipeline
- Changes in public health policy
- Changes in standard of care of patients

Note: list not intended to be exclusive.

Research Programs Continued

2013: What is the extent of the cancer focus in the peer-reviewed research base?

2017: How well are peer-reviewed non-NCI funded projects cancer-focused?

Data Table 2A change:

Simplified – less data for reviewers to shift through

Previously centers listed only the cancer-relevant portion of a grant; now they list the entire grant, and a separate column will report the cancer-relevant portion

Research Programs Continued – Data Table 2A

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Cancer-Relevant Annual Project DC	Program	Program Percent	Annual Program Direct Costs
Alfred L	NCI	1R01CA059736-01	6/1/2016	5/30/2021	Triterpenoids as cancer chemopreventive agents	\$200,000	\$200,000	4	100	\$200,000
Mackall, K	NIGMS	1R01GM065789-01	7/1/2016	6/30/2021	The Molecular Basis of Regulation of Obesity by Nocturnin	\$300,000	\$150,000	2	100	\$150,000

Research Programs Continued

2013: How successful is the Program in fostering productive transdisciplinary and/or translational research collaboration among its members, with members of other programs, and with other external partners?

2017: How collaborative is the program, across the themes/specific aims within the program, with the Center's other programs, with other NCI-designated Cancer Centers, and with other external partners?

2013 and 2017: As appropriate to the type of program, and in addition to research questions of broader applicability, what is the evidence that research relevant to the catchment area is being addressed (e.g., problems affecting racial and ethnic minorities, rural residents, women, children, elderly, persons of low socioeconomic status, cancer sites of high incidence/mortality, environmental exposures, behavioral factors, or other issues)?

Research Programs Continued

2013: How appropriate and effective are the Program leaders in relation to expertise, program management, and time commitment?

2017: How appropriate and effective is the program leader (or leaders) in relation to expertise, program management, and time commitment? If more than one Program Leader, how do the leaders work together to enhance the Program?

For programs with clinical trials:

2013: How successful is the Program in activating interventional trials that make a difference, e.g., advance the field or change medical practice?

2017: What is the impact of the clinical trials in the program (see list above)?

2017 (New): How well do the clinical trials in the program address cancer research issues and special populations in the Center's catchment area?

Research Programs Continued

2013: How successful is the Program in moving research through the translational continuum, via coordination across clinical funding mechanisms of the NCI or collaborations with industry or other partners?

2017: How successful is the program in translating research, particularly the basic science in the program and/or the Center's other programs, and in using clinical observations to inform basic and population science research?

2013: Is the program participating in accrual to, and leadership of, National Clinical Trials Network (NCTN) trials appropriate to its scientific agenda?

2017: Is the program a leader of the NCI-supported clinical trial networks, such as the National Clinical Trials Network (NCTN), the Early Therapeutic Clinical Trials Network (ETCTN), etc.?

Does the program participate in accrual to NCI-supported clinical trials, particularly NCTN, ETCTN, NCORP?

2013 and 2017: How appropriate is overall accrual to trials (taking into consideration those with unique accrual targets, e.g., rare cancers, targeted therapies)?

Shared Resources

- 6 page limit (down from 12)
- New (old) review procedure
- New review criteria (in italics)
 - *How well does the shared resource provide access to state-of-the-art capabilities?*
 - *How critical is the shared resource to the research of the Center?*
 - *Are the future plans for the shared resource aligned with member needs?*
 - What are the quality and cost efficiency of the services provided by the shared resource?
 - How accessible to Center members, including consortium members, is the shared resource?
 - How appropriate are the qualifications of staff and their time commitment?
 - For institutionally managed resources, how accessible are the services for cancer center members?

Comprehensiveness

Prior to 2012: Stage 2 review of comprehensiveness

- Education and Training of Biomedical Researcher and Health Care Professionals
- Community Service, Outreach, and Dissemination

2012-2016: these concepts embedded in existing components as review criteria

- Education and Training into Senior Leaders, Organizational Capabilities, Comprehensiveness, Research Programs (unofficially)
- Community Service, etc. into “catchment area” in Senior Leaders, Organizational Capabilities, Research Programs, Comprehensiveness

2017: New components

- Cancer Research Career Enhancement and Related Activities (E&T)
- Community Outreach and Engagement (COE)

Cancer Research Career Enhancement and Related Activities

The objectives of the NCI Centers Program are to foster highly interactive cancer research through support of the following:

- Efforts to coordinate and enhance existing cancer research education, training, and career development activities

Cancer Research Career Enhancement and Related Activities

List, in a table format, all active cancer-related research education and training grants competitively funded by sources external to the applicant institution (applicants may use suggested data table format 2A for this purpose, if desired). Grants are listed alphabetically by PD/PI in two parts – active, peer-reviewed funded cancer research education and training grants and active non-peer reviewed education and training grants.

Cancer Research Career Enhancement and Related Activities may support:

- Faculty Associate Director of Cancer Research Career Enhancement
- Education Coordinator(s) and other staff that assist in Cancer Research Career Enhancement activities
- Travel to professional meetings for mentees
- Funding for support of activities directly relevant to the core, such as scientific seminar speakers, workshops, short courses, etc.

Cancer Research Career Enhancement and Related Activities

Research Strategy: The Cancer Research Career Enhancement and Related Activities core will coordinate existing research education and training activities at the cancer center and provide additional educational opportunities by supporting travel to scientific meetings, scientific seminars, workshops, and related activities. In this section describe:

- The cancer research career enhancement activities in which the core will be engaged, such as coordinating travel opportunities, seminars, workshops, and related activities
- The process for coordinating existing cancer education and training activities at the center, including with other institutional efforts, and integrating them into programmatic efforts
- The inclusion of special or unusual areas of cancer research education (health disparities, global health, etc.)
- New initiatives and plans for the next funding cycle

Cancer Research Career Enhancement and Related Activities – Review Criteria

- What are the extent and quality of existing cancer research education, training and career development activities at the Center, as appropriate for the type (basic, clinical, or comprehensive) and size of center?
- How well does the center coordinate existing training and career development activities?
- How appropriate is the Center's process for integrating existing cancer education and training of biomedical researchers and health care professionals, including members of underserved populations, into programmatic and shared resource research efforts?
- Is the institutional commitment to the existing cancer education and training activities appropriate?
- How appropriate are proposed activities for the next funding cycle?

Community Outreach and Engagement (COE)

Community Outreach and Engagement may support:

- Faculty Associate Director devoted to center efforts in community outreach and engagement, such as cancer health disparities, recruitment of underserved populations to clinical trials, etc.
- Coordinators of outreach and engagement of local populations
- Coordinators of educational outreach and engagement of local populations
- Personnel, such as patient navigators, who facilitate the inclusion of underserved populations into the Center's clinical research

COE

Cancer Centers occupy a unique role in their communities. They are expected to perform research relevant to their catchment area and engage the populations within their catchment area in the research they conduct and other Center activities.

In the Community Outreach and Engagement, the applicant should describe the aspects in which the Center and its research engages its catchment area, and how the center extends its reach beyond the catchment area.

COE

In this component describe:

- The center's catchment area, including the demographics of its population
- How the catchment area was determined
- The cancer research issues relevant to the catchment area, with particular emphasis on unique or unusual cancer incidence, underserved populations, or cancer health disparities
- How the center engages populations in their catchment area with respect to clinical studies
- The implementation of health policy recommendations, such as tobacco cessation, HPV vaccine uptake, colorectal cancer screening, etc., designed to decrease cancer incidence and mortality rates in the cancer patients they treat and the communities they serve
- How the center addresses cancer health disparities
- As applicable, how the center extends its reach within and beyond its catchment area, through affiliates and other networks that bring the center's expertise to bear on wider populations, rural populations, global cancer research, etc.

COE – Review Criteria

- How appropriately does the Center define its catchment area?
- How well does the Center identify the cancer research issues relevant to its catchment area?
- How well has the Center taken advantage of its catchment area to address challenging questions in cancer research?
- How well has the Center developed processes for including underserved populations in its programmatic research?
- As applicable, are the Center plans for extending its reach within and beyond the catchment area, reasonable?
- How well is the Center taking advantage of appropriate relationships with networks and affiliates?

Community Service, Outreach, and Dissemination (Old Comp. Review)

- Knowledge of the cancer problem in the community served by the Center, including cancer incidence and mortality rates associated with both majority and special populations
- Collaborations
- Outreach activities, including plans for those that address the special problems of the community
- Priority setting and use of available expertise and resources to serve the community in ways that will reduce cancer incidence and mortality
- Efforts to evaluate the impact of development to delivery activities on clinical and public health systems within the center's catchment area

Leadership, Planning, and Evaluation

- Moved Senior Leadership out of Administration and into P&E
- The idea is that senior leaders implement the goals identified in P&E
- Review criteria are the same, except catchment area has been removed
- What will this narrative look like?

Developmental Funds

- Eliminate bridge funding
- Added possibility “Support of early stage clinical investigators”
 - Faculty of all disciplines
 - Do not have to name candidates (unlike Staff Investigators)
 - No limit to number; 20% effort is max
 - Current T or K support no allowed
 - ROI: retention in clinical research, recruitment of patients, participation in NCTN, expansion of trials portfolio, etc.

Developmental Funds - continued

■ New review criteria:

- How effectively has the center used developmental funds in the current funding period to pursue research priorities?
- What has been the return on developmental funds investment in the current funding period (e.g., strategic recruitments, grants, publications, collaborative/translational research, inter-cancer center collaborations, new shared resources, innovative pilot projects (including early phase clinical trials), etc.)?
- How well has the center used developmental funds to pursue innovation and to move in new scientific directions that matches the strategic goals of the center?
- How rigorous are the processes for the use of developmental funds?
- How appropriate are plans for use of future Developmental Funds with respect to the strategic priorities of the center?

Alignment with strategic goals, rigor of allocation, and return on investment

2017 CCSG – what's changed

- Eliminated Early Phase Clinical Research Support – centers may use Developmental Funds to fund early phase studies as pilot projects

Other Changes

Data Table 3 – eliminate “Patients newly enrolled in interventional treatment trials”

Consortium status – portfolio, MOU, fully-functioning partnership, unified PRMS and DSMP, tangible commitments to Center, integrated P&E; defines portfolio (as in “holds a portfolio of peer-reviewed cancer related research grants”) as 7 projects and 5 investigators

Consortium (acceptable/unacceptable)

- Does the consortium partner have adequate peer-review funding to justify inclusion in the Center? Does the consortium partner contribute tangible commitments to the Center? Is the consortium partner fully integrated into the Center, as demonstrated by extensive scientific collaboration and participation in the Center’s research programs? Is the MOU adequate to ensure the stability and integration of the Center? *{How is the scientific mission of the Cancer Center enabled by cancer education of biomedical scientists and health care professionals?}*



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